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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/803,575	03/17/2004	Jerome C. Bressi	HDAC-5005-C1	6120

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EXAMINER

CHANG, CELIA C

ART UNIT	PAPER NUMBER
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.1625

DATE MAILED: 09/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/803,575	Applicant(s) BRESSI ET AL.	
	Examiner Celia Chang	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-95 is/are pending in the application.
- 4a) Of the above claim(s) 1-81 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 82-95 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Applicant's election with traverse of Group I, claims 82-95 in the reply filed on July 26, 2006 is acknowledged. The traversal is on the ground that a newly proposed grouping of the different inventions would not impose burden to the search. This is not found persuasive because applicants' attention is drawn that the basis of restriction was 35 U.S.C. 121 and 372 because the groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. Wherein Annex of Markush practice, **Part 1(f)v**, indicates that

“When dealing with alternatives, if it can be shown that at least *one* Markush alternative is not novel over the prior art, the question of unity of invention shall be reconsidered by the examiner”

The independence and distinctness was found based on prior art of CA 127:17674 which evidenced that the groups lack unity of invention. The search is therefore not coextensive. The proposal by applicants recombines structural diversified compounds into subgroups. Not only the search for such diversified groups is extremely burdensome, upon applicants' suggestion, a preliminary searching evidenced that grouping of benzimidazolylpiperidine and purinylpiperidine further was evidenced that the different “core” having different utility (see CA 134:100881). It would be extreme burden to search such diversified core structural with diverse utility.

The requirement is still deemed proper and is therefore made FINAL.

Claims 82-95, with the species of compound 5 is prosecuted. Claims 1-81 being drawn to the non-elected inventions are withdrawn from consideration per 37 CFR 1.142(b).

2. Claims 82, 85, 87, 89, 92, 94 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims employed the language “comprising” in defining different Markush members of the compounds or moieties. It is improper to use the term “comprising” in reciting members of Markush groups. See MPEP 2173.05(h). The term “consisting of” is recommended.

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3. Claims 82 and 89 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is noted that the ring containing V where at least one V is NR₁₂, while enabled for piperidines, lacks enablement for the remaining subject matter wherein multiple V is NR₁₂. Starting material and how to make such compounds must be provided. Absent of starting material, the public is offered mere language rather than enablement. Ex Parte Moersch 104 USPQ 122. Further the term “2-10” atoms encompassed any atom of the periodic table. No starting material for such compounds wherein L is 2-10 any atom other than “C” can be found.

4. Claim 82 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The scope of “M” cannot be ascertained. Please note that “M” is part of a compound which is structural for the compounds. There is no nexus of the functional limitation i.e. “capable of complexing with a deacetylase catalytic site” as claimed. It is unclear what constitutes such functional moiety. It is recommended that structural delineation for the moiety be clearly identified.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (f) he did not himself invent the subject matter sought to be patented.

Claim 82 is rejected under 35 U.S.C. 102(a) or (f) as being anticipated by Vourloumis et al. Tetrahedron Lett. Supplemented with CA139:133505.

Vourloumis et al. disclosed anticipatory compounds wherein the M moiety is nitro, see fig. 1, p.2807 and formula 8, p.2808.

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The chemical structure of the compounds have been delineated by CA 139:133505. wherein the L is bond, M is nitro, R2, R4, R5 are H, R3 is carbonyl, R12 is carbonyl (RN 569355-55-1).

6. Claims 82-95 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 109-144 of copending Application No. 10/803,580. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims fully embraced the copending scope.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).


7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie, Ph. D., can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang
Sept. 19, 2006

A handwritten signature in black ink, appearing to read 'Celia Chang', with a stylized flourish at the end.

Celia Chang
Primary Examiner
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